PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Thomas McHale and Jan Weber**
Application No.:	**10/767675**
Filed:	**January 29, 2004**
For:	**CATHETER TIP**
Examiner:	**Ryan J. Severson**
Group Art Unit:	**3731**

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Docket No.: S63.2B-10813-US01

APPEAL BRIEF

This is an Appeal Brief for the above-identified Application in which claims 1-26 and 58-60 were rejected in the Final Office Action mailed April 8, 2008. A Notice of Appeal was filed in this case on August 7, 2009. This brief is submitted in accordance with 37 CFR. § 41.37. The fees required under 37 CFR § 41.20(b)(2), and any petition for an extension of time required for filing this brief, are addressed in the accompanying Transmittal Letter.

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(i) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.), One Scimed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

No related appeals or interferences are pending.

(iii) Status of Claims

Claims 1-26 and 58-60 are pending in the application, have been finally rejected and are the subject of this appeal. Claims 27-57 were previously cancelled.

(iv) Status of Amendments

A Response After Final was filed on July 8, 2009, which presented arguments but did not amend the claims. No claim amendments have been filed subsequent to the Final Office Action.

(v) Summary of Claimed Subject Matter

Independent claim 1 recites a catheter comprising a catheter shaft 12 having a proximal end and a distal end 16. See Figure 2 and page 5, lines 21-24. An inflation balloon 44 includes a proximal waist portion 54, a proximal cone portion, a main body portion, a distal cone portion and a distal waist portion 56. See page 7, lines 2-9. A catheter tip 20 includes a guidewire lumen 26 extending therethrough and comprises a proximal end 22, a distal end 24. A proximal shaft portion, a central shaft portion and a distal shaft portion are located between the proximal end 22 and distal end 24. See page 6, lines 26-30. A cross-sectional area of the central shaft portion is defined by a single peripheral layer of catheter tip material extending around said guidewire lumen. The cross-sectional area of the central shaft portion is substantially equal to a cross-sectional area of the proximal shaft portion and substantially equal to a cross-sectional area of the distal shaft portion. See Figure 2. The catheter tip 20 comprises a first recessed portion 34 located between the distal shaft portion and the central shaft portion and a second recessed portion 34 located between the central shaft portion and the proximal shaft portion. See page 6, line 32. Each recessed portion extends around a full outer periphery of the catheter tip 20. See Figure 2. A cross-sectional area of the first recessed portion 34 is less than the cross-sectional area of the central shaft portion. A cross-sectional area of the second recessed portion 34 is less than the cross-sectional area of the central shaft portion. The catheter tip 20 proximal end 22 is coupled to the catheter shaft distal end 16. The balloon distal waist portion 56 is attached to the catheter tip distal shaft portion. See page 7, lines 3-5. The first recessed portion 34 oriented beneath the balloon distal cone portion and the second recessed portion 34 oriented beneath the proximal cone portion. See Figure 2. In an unexpanded state, at least a portion of the balloon 44 is stored in the first recessed portion 34. See page 9, lines 7-15.

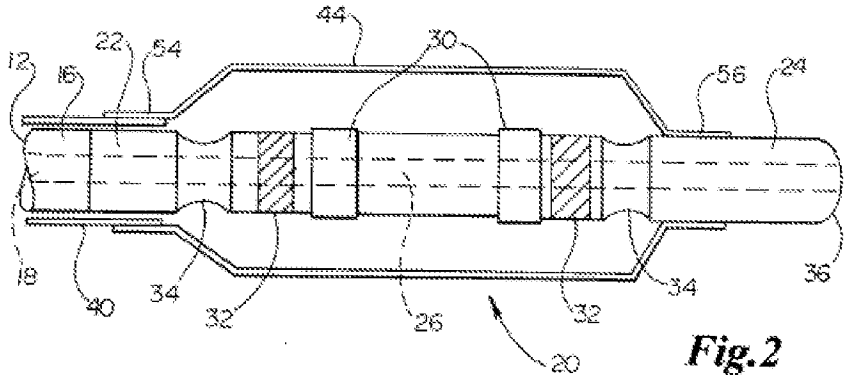


Fig.2

Dependent claim 2 recites at least one marker 32 oriented beneath the balloon main body portion. Claim 3 recites a radiopaque marker and claim 4 recites an MRI marker. See page 8, lines 17-30.

Dependent claim 6 recites at least a portion of the balloon distal cone portion is stored in the first recessed portion 34, and at least a portion of the balloon proximal cone portion is stored in the second recessed portion 34. See page 9, lines 7-15.

Dependent claim 7 recites a hub portion 30 oriented beneath the balloon main body portion, the hub portion 30 having a larger cross-sectional area than the central shaft portion. See page 6, lines 30-32.

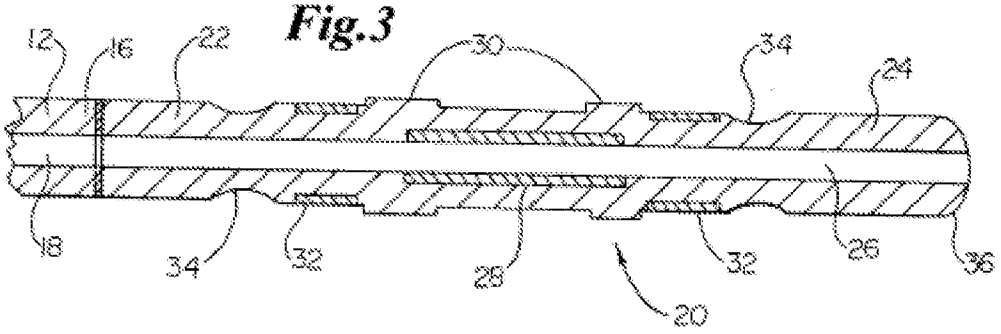
Dependent claim 8 requires that the catheter tip comprises a molded catheter tip and that the hub portion 30 is formed integrally with the catheter tip. See page 7, lines 13-17.

Dependent claim 10 recites a radiopaque marker 32 that is insert molded. See page 7, lines 18-21.

Dependent claim 11 recites an outer surface of a radiopaque marker 32 is flush with an outer surface of said catheter tip 20. See page 8, lines 1-4.

Dependent claim 12 recites a stiffener 28. Dependent claim 13 recites the stiffener is a spring. See Figure 3 and page 7, lines 22-26.

Fig.3



Dependent claim 14 recites a marker region entrained with a radiopaque material. See page 10, lines 29-31.

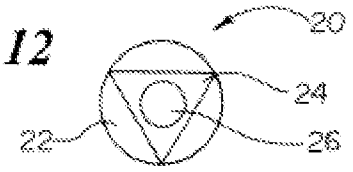
Dependent claim 15 recites a first region and a second region, said first region having greater flexibility than said second region. See page 10, lines 23-24.

Dependent claim 17 recites an outer catheter shaft 40, wherein the balloon proximal waist portion 54 is coupled to the outer catheter shaft 40. See Figure 2 and page 7, lines 3-5.

Dependent claims 21-24 recite various limitations related to stents and stent delivery. See e.g. page 8, lines 8-16.

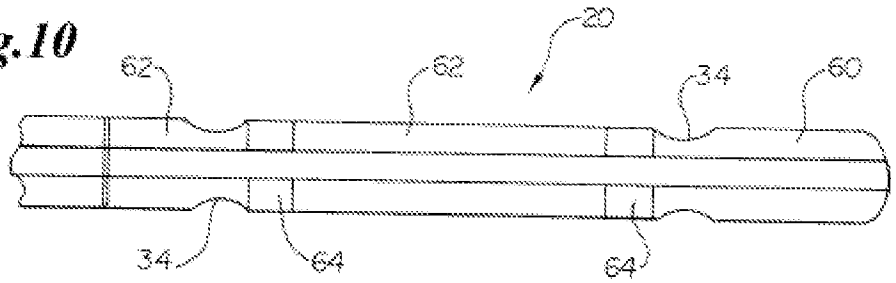
Dependent claim 25 recites a portion of the central shaft portion having a plurality of sides. Dependent claim 26 requires that the central shaft portion is triangular. See Figure 12 and page 11, lines 30-32.

Fig.12



Independent claim 16 recites a catheter shaft 12 having a proximal end and a distal end 16. See Figure 2 and page 5, lines 21-24. An inflation balloon 44 includes a proximal waist portion 54, a proximal cone portion, a distal cone portion and a distal waist portion 56. See page 7, lines 2-9. A catheter tip 20 comprises a proximal end 22, a main shaft portion, a distal shaft portion and a distal end 24. See page 6, lines 26-30. The catheter tip 20 comprises a recessed portion 34, a cross-sectional area of the recessed portion 34 being less than a cross-sectional area of the catheter tip at a location proximal to the recessed portion and at a location distal to the recessed portion. See Figure 2. The recessed portion 34 is oriented beneath the balloon distal cone portion. See Figure 2. In an unexpanded state, at least a portion of the balloon is secured in the recessed portion 34. See page 9, lines 7-15. The catheter tip 20 comprises a first region 60 and a second region 62, said first region 60 having greater flexibility than said second region 62. See Figure 10, provided below, and page 10, line 32-page 11, line 10. The catheter tip proximal end 22 is coupled to said catheter shaft distal end 16. The balloon distal waist portion 56 is attached to said catheter tip distal shaft portion, said catheter tip main shaft portion being substantially coextensive with said balloon. See Figure 2. The second region 62 comprises entrained stiffening fibers selected from a group consisting of polypropylene fibers and polyolefin fibers. See page 11, lines 3-10.

Fig.10



(vi) Grounds of Rejection to be Reviewed on Appeal

Issue 1: Whether the Examiner erred in rejecting claims 1-15, 17-26 and 59-60 under 35 USC § 103 over a combination of Matthews (US 4739769) in view of Wolvek (US 4276874).

Issue 2: Whether the Examiner erred in rejecting claims 2-4, 7-10 and 14 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Fulton (US 6074374).

Issue 3: Whether the Examiner erred in rejecting claim 11 under 35 USC § 103 over Matthews in view of Wolvek and Fulton and further in view of Follmer (US 5728065).

Issue 4: Whether the Examiner erred in rejecting claims 12, 13, 15 and 17 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Follmer.

Issue 5: Whether the Examiner erred in rejecting claim 59 under 35 USC § 103 over Matthews in view of Wolvek and Follmer and further in view of Chee (US 5906606).

Issue 6: Whether the Examiner erred in rejecting claims 21-24 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Imran (US 5766203).

Issue 7: Whether the Examiner erred in rejecting claims 25 and 26 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Hamilton (US 6514228).

Issue 8: Whether the Examiner erred in rejecting claims 16 and 58 under 35 USC § 103 over Matthews in view of Follmer and Chee.

(vii) Argument

Issue 1: Whether the Examiner erred in rejecting claims 1-15, 17-26 and 59-60 under 35 USC § 103 over a combination of Matthews (US 4739769) in view of Wolvek (US 4276874).

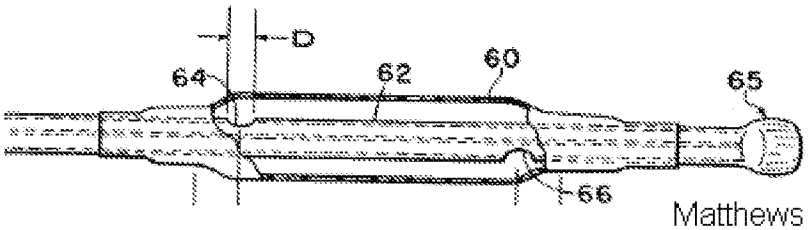
The Examiner rejected claims 1, 5, 6, 18-20 and 60 under 35 USC § 103 over Matthews in view of Wolvek, and rejected several other dependent claims over Matthews in view of Wolvek and further in view of additional reference(s). The rejections that cite additional reference(s) are discussed under Issues 2-7; however, since all of the rejections relevant to Issues 1-7 rely upon a primary combination of Matthews and Wolvek, Applicants' assertions under Issue 1 are also relevant to Issues 2-7.

The Examiner erred in rejecting claims under 35 USC § 103 over Matthews in view of Wolvek because the combination does not disclose or suggest each limitation of the rejected claims, and because the rejection fails to articulate any reasoning or rationale as to why a person of skill in the art would have been motivated to modify the Matthews device as proposed by the Examiner. Further, the modification to Matthews proposed by the Examiner would be detrimental to the ability of the Matthews device to perform its intended function. Therefore, a person of ordinary skill in the art would not have been motivated to modify Matthews, and even if the proposed modifications were performed, the resulting device would not meet the limitations of the rejected claims.

Independent claim 1 recites "a catheter tip having a guidewire lumen extending therethrough."

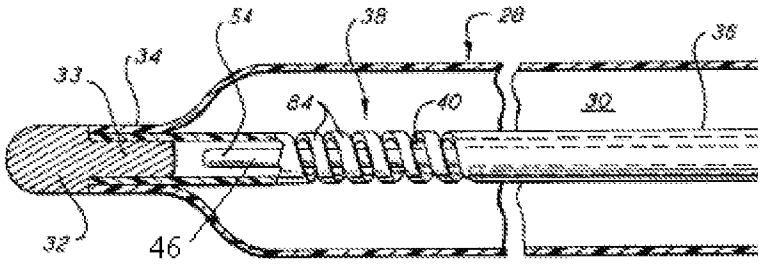
Neither Matthews nor Wolvek discloses or suggests a catheter tip having a guidewire lumen extending therethrough.

The Matthews device does not use a guidewire, and the tip 65 does not have a guidewire lumen. See e.g. excerpt from Figure 6 of Mathews, provided below.



Matthews Fig. 6

The Wolvek rigid tip 32 is a solid member that does not have a guidewire lumen. See e.g. excerpt from Figure 1 of Wolvek, provided below, annotated to include reference character 46.



Wolvek FIG. 1

Further, omission of a guidewire lumen from the tip 32 is necessary in the Wolvek Elongatable Balloon Catheter (see title), as the rigid tip 32 provides a means for elongation of the balloon. When the rod 46 is displaced by an operator, the distal end 54 of the rod 46 abuts the rigid tip 32. Continued movement of the rod causes the balloon to stretch axially as the helical coil 84 portion of the catheter elongates. See Wolvek at column 6, lines 54-61, and compare Wolvek Figures 1 and 3. Thus, the Wolvek tip intentionally omits a lumen.

"Obviousness requires a suggestion of all limitations in a claim." CFMT, Inc. v. Yieldup Intern. Corp., 349 F.3d 1333, 1342 (Fed. Cir. 2003).

The Examiner asserts that the Wolvek rod 46 is a guidewire, and that the lumen for the rod is considered a guidewire lumen. See Advisory Action at page 3.

The elongation rod 46 is not a guidewire. It does not function as a guidewire and would not be considered a guidewire by a person of ordinary skill in the art. However, even if a lumen in the Wolvek device is considered to be a guidewire lumen, the modification to Matthews proposed by the Examiner (discussed in detail below) does not incorporate the Wolvek lumen into the Matthews device. Thus, even if the modification to Matthews proposed by the Examiner was performed, the resulting device would not include a guidewire lumen, and would not meet the limitations of claim 1 or any claim dependent therefrom. Therefore, Applicants assert that the Examiner has not presented a *prima facie* case of obviousness against claim 1 or any claim dependent therefrom.

Insufficient Rationale to Support Proposed Modification

The Examiner has not provided sufficient rationale as to why a person of ordinary skill in the art would have been motivated to modify the Matthews device as proposed in the rejection. The rejection stems from an impermissible hindsight attempt to meet the limitations of the pending claims, as the Examiner does not provide any reason for making the modification or discuss any benefit that would result from the modification. Further, the modification proposed by the Examiner would change critical dimensions of the Matthews device, likely rendering the device unsuitable for its intended purpose of determining tissue pressure.

Matthews teaches a transducer system for measuring tissue pressure, such as the pressure in muscle tissue in humans and other animals. See column 1, lines 10-18 and Figure 7.

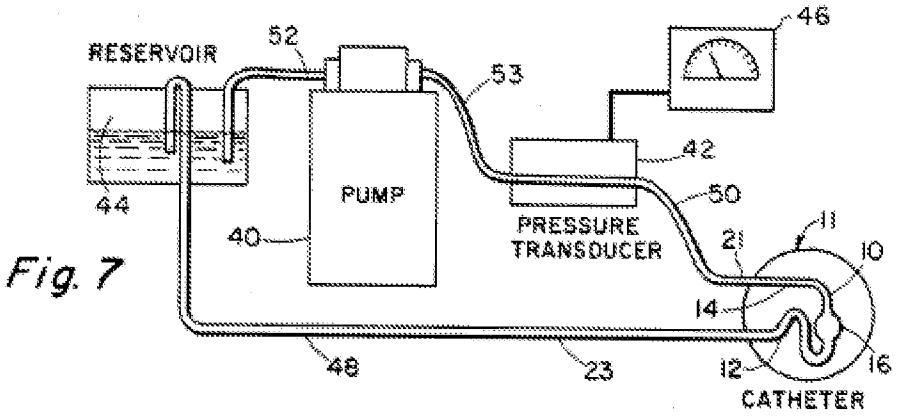


Fig. 7

Wolvek teaches an elongatable balloon catheter suitable for intra-aortic pumping. See e.g. column 1, lines 7-17 and excerpt from Figure 1 provided below.

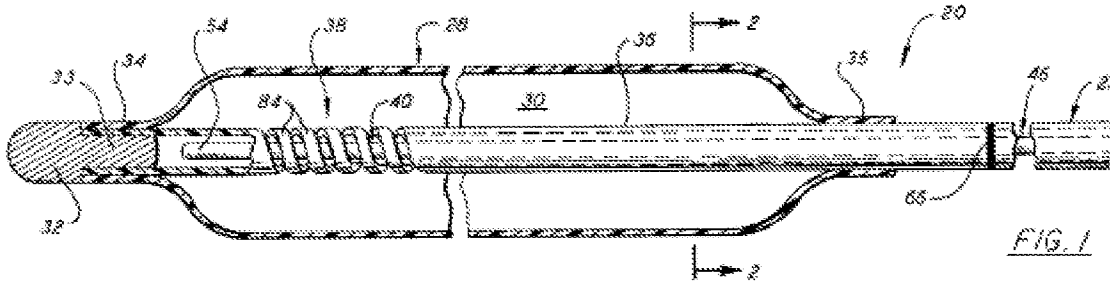


FIG. 1

Claim 1 requires a catheter tip comprising first and second recessed portions, and recites, "each recessed portion extending around a full outer periphery of the catheter tip."

The rejection characterizes ports 64 and 66 of the Matthews tissue pressure measurement system as the claimed "recessed portions." See Final Office Action at page 2 and

Matthews Figure 6, provided below.

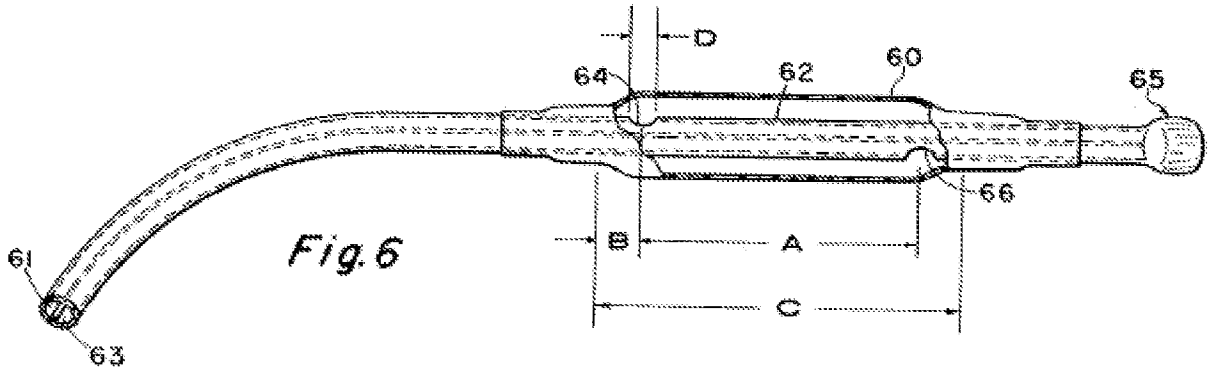


Fig. 6

The Examiner argues that a person of ordinary skill in the art would have found it obvious to modify the Matthews ports 64 and 66 to extend around the catheter in a manner similar to the helical slit 40 disclosed by Wolvek. See Final Office Action at page 2 and Wolvek Figure 1, provided above. This assertion is traversed.

The rejection clearly stems from an impermissible hindsight attempt to meet the claim requirement that the recessed portions extend about the periphery of the catheter tip. A person of ordinary skill in the art would have found no reason to modify Matthews as proposed by the Examiner because 1) no benefit would result from the modification; 2) the modification would add unnecessary expense and complexity; and 3) the modification would likely be detrimental to the ability of the Matthews device to accurately measure tissue pressure.

Further, the Matthews and Wolvek devices are designed for different uses and have different functions, and their individual features are not readily compatible with one another. The Examiner has failed to consider the applied references as a whole, as evidenced by the proposed modification that dissects a component part out of the Wolvek device and proposes to use the dissected feature in the Matthews device.

In the Wolvek device, the helical slit 38 allows the balloon to be elongated. See Wolvek at column 6, lines 54-61. As the balloon is elongated, the helical slit 38 stretches as shown in Figure 3, provided below.

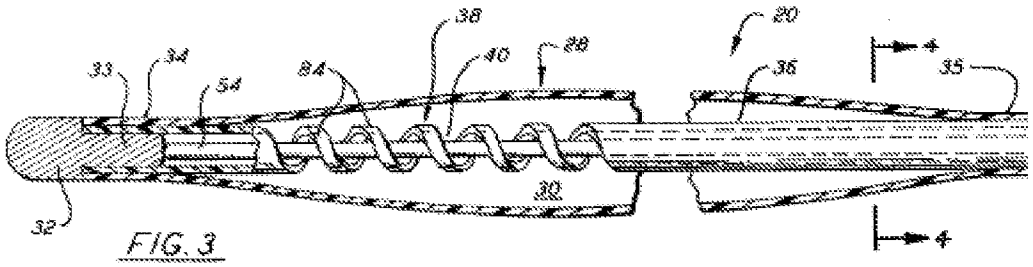
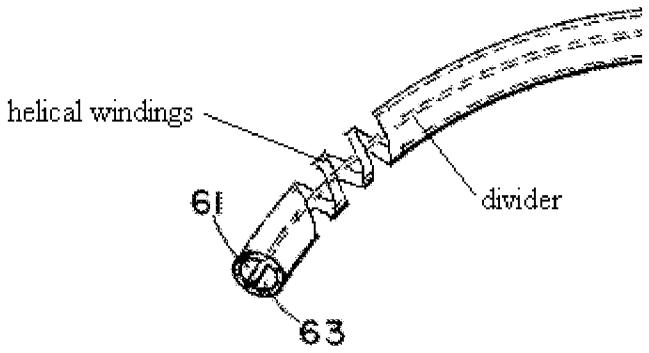


FIG. 3

If helical slits were incorporated into the Matthews catheter, the elongatable functionality of the helical slit would be destroyed. The Matthews catheter includes two lumens, separated by an internal divider. The divider would remain attached to any helical windings of the catheter, and would brace the windings structurally, preventing elongation of the helix. See e.g. excerpt from Matthews Figure 6 below, modified to illustrate a helical winding. The modification proposed by the Examiner would negate any benefits that are provided by the helix in the Wolvek device.



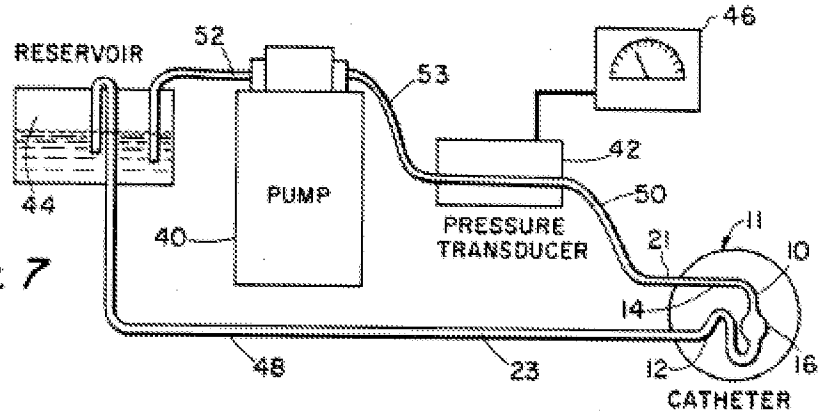
In proposing the modification to Matthews, the Examiner does not rely on any teachings from Wolvek as to benefits of the helical slit. Although the helical slit is functional and key to operation of the Wolvek device, the benefit and functionality would not be carried over into the Matthews device. Thus, the rejection does not stem from any motivation to improve the Matthews device. Instead, the rejection stems from an impermissible hindsight attempt to dissect and import a feature from Wolvek that the Examiner considers to inherently meet a limitation from the rejected claims – the particular limitation that the Examiner admits is missing from the Matthews disclosure. See e.g. Final Office Action at page 2.

Modifying Matthews to have helical ports would add cost and complexity to the device. The Examiner has not mentioned any benefit to Matthews that would result from the modification. Therefore, the rejection has not provided any rationale as to why a person of

ordinary skill in the art would even attempt such a modification.

Further, the modification would likely inhibit the ability of the Matthews device to accurately measure tissue pressure. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Fig. 7



The Matthews device includes a balloon 16 that is inserted into tissue, such as muscle tissue, which is indicated by reference character 11 in Figure 7 above. A pump 40 forces fluid through a first catheter/supply lumen 14, through the balloon 16 and out a second catheter/return lumen 12. When the tissue 11 exerts pressure onto the balloon 16 that is greater than the pressure within the balloon 16, the balloon 16 deforms inwardly, which impedes fluid flow through the system. A pressure transducer 42 monitors pressure in the system and can determine pressure of the tissue 11 based upon the pressure and flow levels. See e.g. column 4, line 5-column 5, line 8.

Matthews Figure 6, recreated below, illustrates a preferred embodiment of the Matthews catheter/balloon. See e.g. column 3, lines 51-52. The lumen ports 64, 66 are located and sized with specific dimensions that allow the device to operate. For example, Matthews states, "Care must be exercised that the hole 64 is not too close to the end so that any change in compliance due to the sealing will not change the compliance of the bubble 60. The design, having the measurements shown, has worked satisfactorily…." See column 6, lines 3-22.

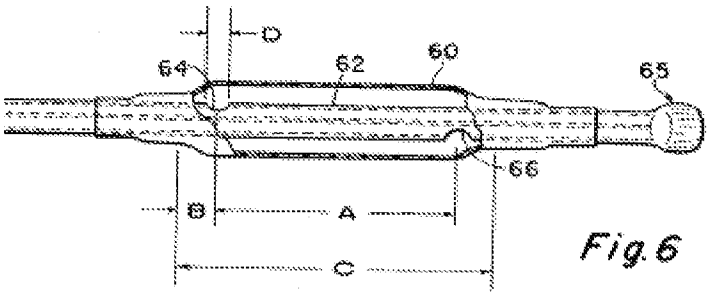
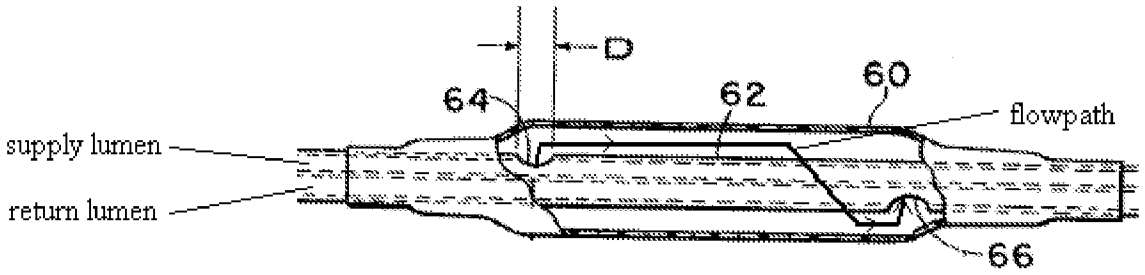


Fig. 6

CATHETER DIMENSIONS (IN MILLIMETERS)			
A	B	C	D
6.17	4.32	13.41	1.78

A person of ordinary skill in the art would recognize the importance of the fluid flowpath within the balloon 60 between the lumen ports 64, 66 – the path that must be taken by the fluid as it flows from the supply lumen at port 64 to the return lumen at port 66. See e.g. excerpt from Figure 6 below, marked to show a flowpath. As taught by Matthews, the device provides a predetermined flowpath that necessarily becomes constricted when external pressures collapse the balloon. This constriction causes slight changes to fluid flow and pressure, allowing the pressure transducer to measure tissue pressure.



Modifying Matthews as proposed in the rejection would modify each of the dimensions A, B, C, D called out in Figure 6, changing the critical fluid flowpath and interfering with the device's ability to perform its intended function. See e.g. Figure 6 provided below, modified to illustrate helical windings incorporated into the device.

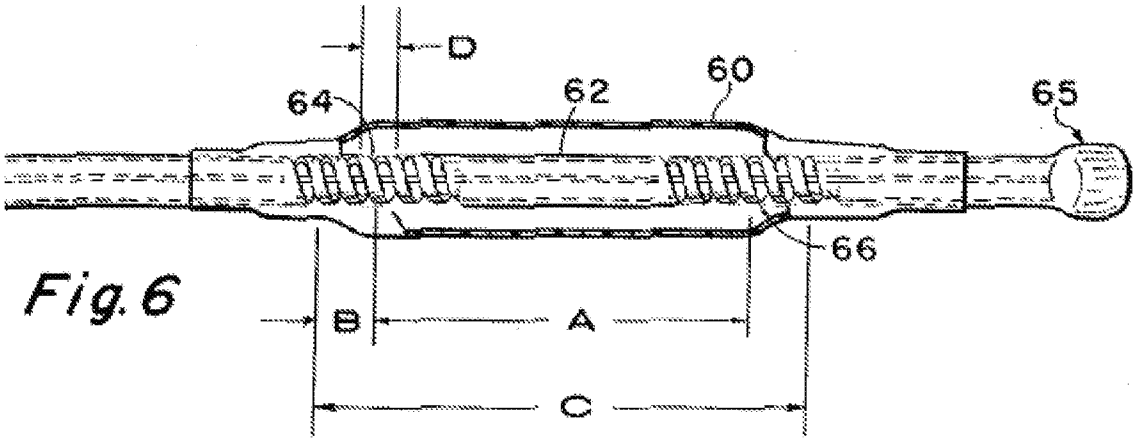
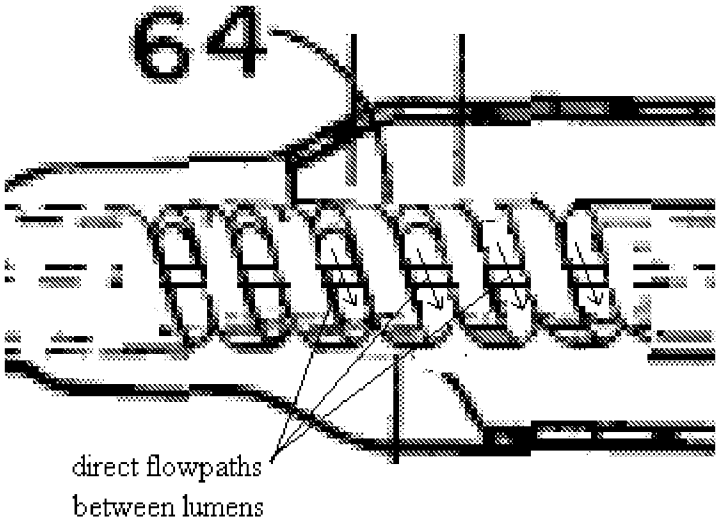


Fig. 6

In the original Matthews device, each port 64, 66 is in fluid communication with a separate fluid lumen. Changing each port 64, 66 to extend helically effectively modifies each port 64, 66 to communicate with both lumens. The modification effectively places several ports in fluid communication with both lumens at both ends of the balloon 60. The modification also provides several direct fluid flow paths between the supply lumen and the return lumen. See e.g. detail of Examiner's proposed modification provided below.



A person of ordinary skill in the art would recognize that the newly created direct flowpaths, illustrated above, are not necessarily affected by external pressure applied to the balloon. Even if the balloon was highly constricted, the fluid would still have several direct flowpaths between the lumens, and the constriction would not necessarily change fluid flow and pressure. Therefore, the proposed modification likely renders the Matthews device unsuitable for its intended function of measuring tissue pressure.

When these drawbacks are considered along with the Examiner's failure to provide any benefit resulting from the modification or any reason for the modification other than a hindsight attempt to meet the limitations of the pending claims, it is clear that a person of ordinary skill in the art would not have been motivated to modify Matthews as proposed by the Examiner.

The Examiner argues that the combination of Matthews and Wolvek is "merely a combination of known prior art elements," and cites to KSR. See Office Action at page 2. Contrary to the Examiner's assertion, KSR does not allow claims to be rejected based on conclusory statements that combinations of prior art elements are merely possible.

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) cited with approval in KSR.

The Examiner has not identified a single reason that would have actually prompted a person of ordinary skill in the art to modify Matthews using teachings from Wolvek as proposed in the rejection. Therefore, the Examiner has not presented a *prima facie* case of obviousness against any of the claims rejected over the primary combination of Matthews and Wolvek.

Applicants request that the Board reverse the rejections asserted against claims 1, 5, 6, 18-20 and 60 over Matthews in view of Wolvek. Applicants further request that the Board reverse of all rejections discussed under Issues 2-7 below, which all rely upon the primary combination of Matthews and Wolvek discussed above under Issue 1.

Issue 2: Whether the Examiner erred in rejecting claims 2-4, 7-10 and 14 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Fulton (US 6074374).

The Examiner erred in rejecting claims 2-4, 7-10 and 14 over Matthews and Wolvek and further in view of Fulton because a person of ordinary skill in the art would not have been motivated to add Fulton's radiopaque marker to the Matthews tissue pressure measurement system.

Fulton teaches a radiopaque marker 69 "such as a band of platinum iridium," and further states, "Under fluoroscopic observation, the marker 69 can be observed." See Figure 3, provided below, and column 5, lines 41-47.

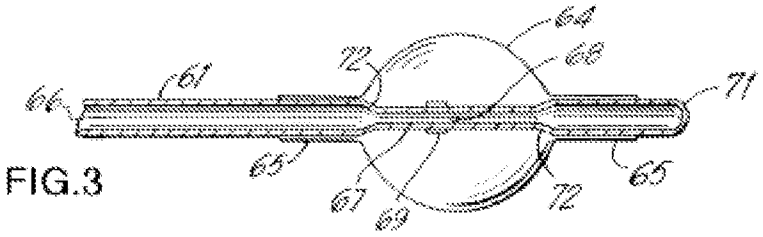


FIG.3

The Examiner has characterized Fulton's radiopaque marker 69 as both a "marker" and a "hub portion," as recited in the rejected claims. The Examiner asserts that it would have been obvious to incorporate the radiopaque marker 69 into the Matthews tissue pressure

measuring device "to allow correct placement of the catheter and balloon at the treatment site." See Office Action at page 3.

A person of ordinary skill in the art would recognize that a radiopaque marker is not necessary in the Matthews device because the Matthews device is not viewed under fluoroscopy. Adding a radiopaque marker to Matthews would add a manufacturing step and increase costs, as Fulton teaches radiopaque markers made from precious metals, without providing any benefit.

The Fulton device is used in minimally invasive surgeries, wherein an elongate delivery catheter is introduced into the body through a small incision and advanced through the vascular system to a treatment site. See e.g. column 1, lines 15-18. Typically in such surgeries, the treatment site must be viewed using an imaging device, such as a fluoroscope. As taught by Fulton, the radiopaque marker 69 is visible through a fluoroscope.

Conversely, the Matthews device is not used for minimally invasive surgeries and is not advanced through the vascular system. The Matthews tissue pressure measuring device is inserted into the tissue from the surface, typically to depth of only 3 to 6 inches. See column 4, lines 9-11. Matthews does not disclose or suggest that fluoroscopy is ever used, and a person of ordinary skill in the art would recognize that fluoroscopy is not necessary when using the Matthews device. Therefore, a person of ordinary skill in the art would not have been motivated to add a radiopaque marker to the Matthews device, as asserted by the Examiner. The Examiner's reasoning for making the modification, allegedly to allow correct placement of the Matthews device at the treatment site, is pretextural, and the Examiner has not articulated any reasoning that would have actually motivated a person of ordinary skill in the art to make the modification proposed.

Therefore, the Examiner has not presented a *prima facie* case of obviousness against the rejected claims, and Applicants request that the Board reverse the Examiner's rejection of claims 2-4, 7-10 and 14 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Fulton.

Dependent Claim 8

Claim 8 recites, "wherein said catheter tip comprises a molded catheter tip and said

hub portion is formed integrally with the catheter tip."

The Examiner characterizes Fulton's radiopaque marker 69 as a "hub portion" and proposes to incorporate it into the Matthews tissue pressure measuring balloon.

Even if the modification proposed by the Examiner was made, the resulting device would not meet the limitations of claim 8, as the resulting "hub portion" would be made from a different material than the Matthews catheter tip and would not be integrally formed with the tip. The applied references do not disclose or suggest an integrally formed hub portion as recited in claim 8.

Applicants request that the Board reverse the Examiner's rejection of claim 8 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Fulton.

Dependent Claim 10

Claim 10 recites, "wherein said radiopaque marker is insert molded." Insert molding, for example when a radiopaque marker is placed into a mold cavity prior to molding of a catheter tip, is discussed in the specification, for example at page 7, line 29-page 8, line 4.

The applied references do not disclose or suggest insert molding, and therefore do not disclose or suggest each limitation of claim 10. Even if the modification to Matthews proposed by the Examiner was made, the resulting device would not meet the limitations of claim 10.

A person of ordinary skill in the art would recognize that a radiopaque marker that has been insert molded can be superior to a traditionally applied radiopaque marker. Markers are often crimped or swaged onto a catheter, subjecting the marker to stress and strains. When a marker is insert molded, it is not strained in the same way. Therefore, use of insert molded markers on a catheter can be safer than crimped or swaged markers.

Applicants request that the Board reverse the Examiner's rejection of claim 10 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Fulton.

Issue 3: Whether the Examiner erred in rejecting claim 11 under 35 USC § 103 over Matthews in view of Wolvek and Fulton and further in view of Follmer.

The Examiner's rejection of claim 11 relies upon the reasoning used in the

rejections discussed above under Issues 1 and 2. If the Board agrees with Applicants' remarks under either Issues 1 or 2, Applicants request that the Board reverse the rejection of claim 11 based upon the previously asserted arguments.

The rejection of claim 11 does not present a reasonable expectation of success. Claim 11 recites, "wherein an outer surface of said radiopaque marker is flush with an outer surface of said catheter tip."

The Examiner asserts, "it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert mold flush the marker of Follmer et al. with the tip of the combination of Matthews et al., Wolvek et al., and Fulton to create a tip that has a low profile yet can be located and guided using conventional imaging techniques." See Final Office Action at pages 3-4.

Thus, the Examiner proposes to add a radiopaque marker to Matthews (e.g. Figure 6, provided below) that is flush with an outer surface of the catheter shaft via insert molding.

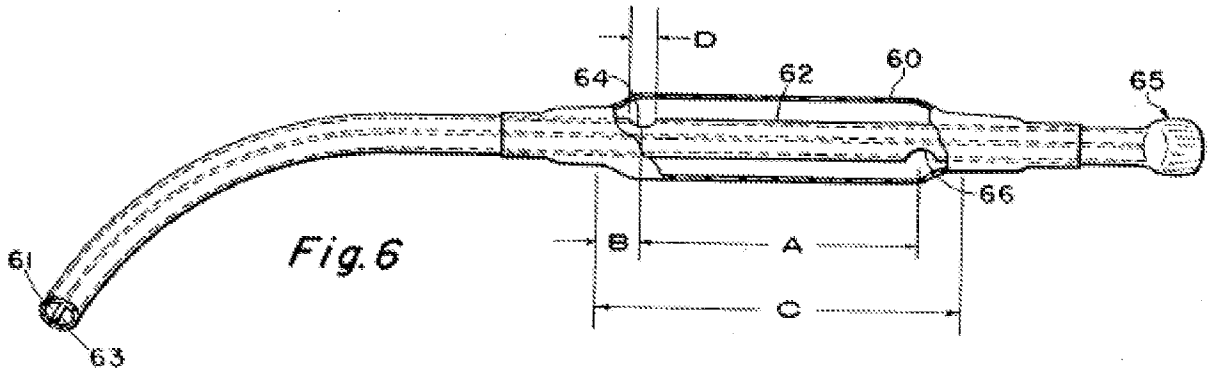


Fig. 6

It is unclear how the catheter of Matthews would be formed using a process that would allow for insert molding. A person of ordinary skill in the art would recognize that the dual lumens 61, 63 in the Matthews catheter would be difficult to form using traditional molds, and that the catheter is likely formed by extrusion. Further, it is unclear how the radiopaque marker would be made flush with the catheter shaft. Due to the thin wall of the Matthews catheter, it appears that the catheter wall thickness must be increased in order to have a marker be flush.

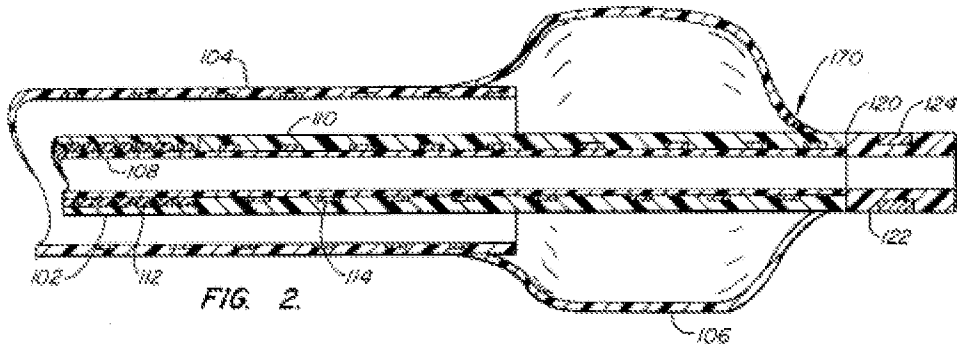
As discussed under Issue 2, fluoroscopy is not used with the Matthews device and a radiopaque marker is not needed. In view of this, as well as the modifications to the Matthews catheter that would be necessary to achieve a flush mount, and the lack of an expectation of success in trying to insert mold a marker into the Matthews dual lumen catheter, Applicants assert

that the Examiner has not presented a *prima facie* case of obviousness against claim 11. Applicants request that the Board reverse the rejection of claim 11.

Issue 4: Whether the Examiner erred in rejecting claims 12, 13, 15 and 17 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Follmer.

The Examiner erred in rejecting claims 12, 13, 15 and 17 because a person of ordinary skill in the art would not have been motivated to stiffen the catheter of the Matthews device as proposed in the rejection.

Follmer teaches a stiffened catheter having reinforcing layers 112, 114 that stiffen the catheter. Region 112 can provide greater stiffness than region 114. See e.g. column 6, line 66-column 7, line 10 and Figure 2, provided below.

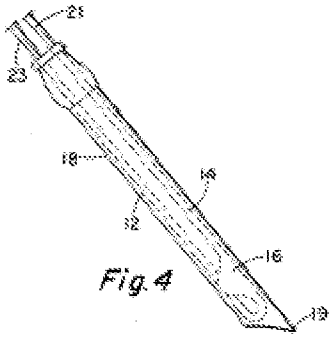


The Examiner asserts that it would have been obvious to form the Matthews device with two regions of different stiffness "to create a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device." See Final Office Action at page 4.

A person of ordinary skill in the art would not add stiffeners to the Matthews device because they are unnecessary. Such a modification would add cost and complication without providing any benefit.

As noted by the Examiner, the Follmer stiffeners are useful in delivery catheters that are used in minimally invasive surgeries, wherein the catheters must be advanced through a tortuous network of vessels in order to reach a treatment site. However, such stiffness is not a design consideration of the Matthews tissue pressure measuring device. The addition of stiffeners to Matthews would not provide any benefits. The Matthews device is not advanced through

vessel lumens in the way of a delivery catheter, but is instead inserted directly into the tissue to be measured, for example using a needle 18. See e.g. column 3, lines 8-11 and Figure 4, provided below.



Therefore, there is no need for stiffened regions in the Matthews device, and a person of ordinary skill in the art would not be motivated to add stiffeners or to create regions of varying stiffness. The Examiner has not articulated a reason that would have motivated a person of skill in the art to modify Matthews as proposed, and a *prima facie* case of obviousness has not been presented. Applicants request that the Board reverse the rejection of claims 12, 13, 15 and 17 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Follmer.

Dependent Claim 17

Claim 17 requires that the claimed device further comprises "an outer catheter shaft, wherein said balloon proximal waist portion is coupled to said outer catheter shaft."

The limitations of claim 17 are not discussed by the Examiner, and the Examiner has not proposed any modification to Matthews that would result in the structure recited in claim 17. Thus, a *prima facie* case of unpatentability has not been presented.

Applicants request that the Board reverse the Examiner's rejection of claim 17.

Issue 5: Whether the Examiner erred in rejecting claim 59 under 35 USC § 103 over Matthews in view of Wolvek and Follmer and further in view of Chee.

The rejection of claim 59 relies upon the reasoning used in the rejections discussed above under Issue 4. If the Board agrees with Applicants' remarks under Issue 4, Applicants

request that the Board reverse the rejection of claim 59 based upon the previously asserted arguments.

Issue 6: Whether the Examiner erred in rejecting claims 21-24 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Imran.

The Examiner erred in rejecting claims 21-24 because a person of ordinary skill in the art would not have been motivated to use the Matthews tissue pressure measurement device as a stent delivery catheter.

Claims 21-24 include various limitations relevant to stent delivery. The Examiner admits that Matthews and Wolvek do not discuss stent delivery, but asserts that in light of Imran, it would have been obvious to use the Matthews device as modified by Wolvek as a stent delivery catheter.

The prior art can only be combined to reject claims as *prima facie* obvious when there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

A person of ordinary skill in the art would not use the Matthews device to deliver a stent because it is not a stent delivery catheter. The modification proposed by the Examiner would not work. The rejection clearly stems from an impermissible hindsight attempt to reach the subject matter of the rejected claims, and a *prima facie* case of obviousness has not been presented.

Applicants request that the Board reverse the rejection of claims 21-24 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Imran.

Issue 7: Whether the Examiner erred in rejecting claims 25 and 26 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Hamilton.

The Examiner erred in rejecting claims 25 and 26 because the teachings of Hamilton would not motivate a person of ordinary skill in the art to modify Matthews as proposed by the Examiner.

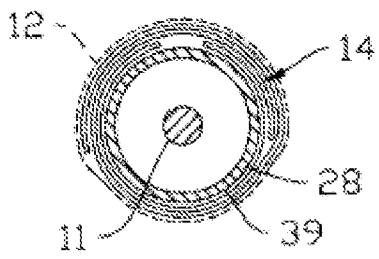
Claim 26 requires a portion of the catheter shaft to have a triangular shape.

The Examiner has applied Hamilton for the teaching of a triangular cross-section

and proposes to modify Matthews to have the triangular shape; however, the Examiner has not articulated any reason why a person of ordinary skill in the art would have been motivated to perform the modification, and has not adequately explained how the modification would be accomplished.

Hamilton teaches that in a dilatation/stent delivery balloon catheter, the deflated balloon often abuts an inner catheter shaft. The small gap 39 that is left between the catheter and balloon causes resistance to the inflation medium as it flows into the balloon to expand the balloon. See Figure 3B, provided below, and column 4, lines 34-45.

Fig.3B



The resistance resulting from the small gap 39 causes the balloon to inflate in a longitudinal wedge shape, wherein proximal portions of the balloon inflate faster than distal portions. In some instances, the wedge shape can force a stent to move longitudinally with respect to the balloon. See column 4, lines 46-56.

To prevent the small gap 39, Hamilton forms the catheter in a shape that creates larger gaps 86, 88, 90. See e.g. Figures 9B-9D and column 7, lines 15-42.

Fig.9B

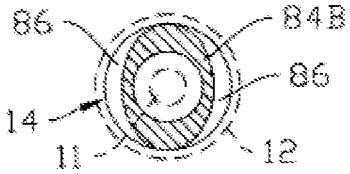


Fig.9C

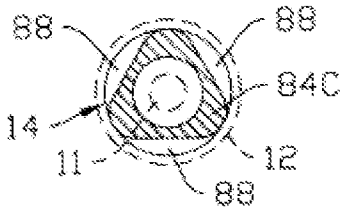
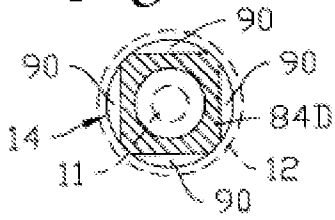


Fig.9D



A person of ordinary skill in the art would not have been motivated to modify the Matthews tissue pressure measuring device based upon the teachings of Hamilton because the teachings are not relevant – the Matthews device does not deliver stents and does not have a

problem of stents translating position with respect to the balloon. There is no reason to modify Matthews as proposed by the Examiner, and the Examiner has not discussed any benefit that would result from the modification. Thus, the proposed modification stems from an impermissible hindsight attempt to reach the subject matter of the rejected claims.

Further, the Matthews device includes two lumens and a divider, whereas the Hamilton catheter includes a single main inflation lumen. The rejection does not discuss how the Matthews catheter would be modified to achieve the Hamilton shape while preserving pressure measuring functionality.

Applicants request that the Board reverse the Examiner's rejection of claims 25 and 26 under 35 USC § 103 over Matthews in view of Wolvek and further in view of Hamilton.

Issue 8: Whether the Examiner erred in rejecting claims 16 and 58 under 35 USC § 103 over Matthews in view of Follmer and Chee.

The Examiner erred in rejecting claims 16 and 58 because the applied references do not disclose or suggest entrained stiffening fibers of polypropylene or polyolefin.

Claim 16 recites, "wherein said second region comprises entrained stiffening fibers selected from a group consisting of polypropylene fibers and polyolefin fibers."

"Obviousness requires a suggestion of all limitations in a claim." CFMT, Inc. v. Yieldup Intern. Corp., 349 F.3d 1333, 1342 (Fed. Cir. 2003).

The applied references do not disclose or suggest the entrained stiffening fiber materials recited in claim 16. The Office Action admits that Matthews and Follmer do not disclose or suggest the recited materials, but asserts that Chee renders the recited materials obvious. See Office Action at page 5.

The Examiner cites to Chee column 7, lines 32-34 (see Final Office Action at page 5), which recites, "Suitable nonmetallic ribbons or wires include materials such as those made of polyaramides (Kevlar), polyethylene terephthalate (Dacron), or carbon fibers."

Thus, Chee teaches polyaramides, polyethylene terephthalate and carbon fibers; however, a person of ordinary skill in the art would recognize that Chee does not disclose "polypropylene fibers" or "polyolefin fibers" as recited in claim 16.

The Examiner has not provided a prior art teaching of the claimed materials, or

provided any prior art showing that the claimed materials would be interchangeable with the materials disclosed in the applied references. Thus, there is nothing in the rejection that would allow a person of ordinary skill in the art to reach the subject matter of the rejected claims.

Therefore, the Examienr has not presented a *prima facie* case of obviousness against claim 16. Claim 58 depends from claim 16 and is patentable over Matthews in view of Follmer and Chee for at least the reasons discussed with respect to claim 16. Applicants request that the Board reverse the rejection of claims 16 and 58 under 35 USC § 103.

Argument Conclusion

Based on at least the foregoing arguments, Applicants respectfully assert that the rejections presented by the Examiner fail to establish a *prima facie* case of obviousness against any of the pending claims. Accordingly, Applicants respectfully request that the Board reverse all of the rejections asserted by the Examiner.

Respectfully submitted,

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(viii) Claims Appendix

1. A catheter comprising:

a catheter shaft having a proximal end and a distal end;

an inflation balloon having a proximal waist portion, a proximal cone portion, a main body portion, a distal cone portion and a distal waist portion; and

a catheter tip having a guidewire lumen extending therethrough, the catheter tip comprising a proximal end, a distal end, a proximal shaft portion, a central shaft portion and a distal shaft portion, a cross-sectional area of the central shaft portion defined by a single peripheral layer of catheter tip material extending around said guidewire lumen, said cross-sectional area of the central shaft portion being substantially equal to a cross-sectional area of the proximal shaft portion and substantially equal to a cross-sectional area of the distal shaft portion, said catheter tip comprising a first recessed portion located between the distal shaft portion and the central shaft portion and a second recessed portion located between the central shaft portion and the proximal shaft portion, each recessed portion extending around a full outer periphery of the catheter tip, a cross-sectional area of the first recessed portion being less than said cross-sectional area of the central shaft portion, a cross-sectional area of the second recessed portion being less than said cross-sectional area of the central shaft portion, said catheter tip proximal end being coupled to said catheter shaft distal end, said balloon distal waist portion being attached to said catheter tip distal shaft portion; the first recessed portion oriented beneath the balloon distal cone portion and the second recessed portion oriented beneath the proximal cone portion, in an unexpanded state at least a portion of the balloon being stored in the first recessed portion.

2. The catheter of claim 1, further comprising at least one marker oriented beneath the balloon main body portion.

3. The catheter of claim 2, wherein said marker is a radiopaque marker.

4. The catheter of claim 2, wherein said marker is an MRI marker.

5. The catheter of claim 1, wherein said catheter tip distal end comprises a radiused tip.

6. The catheter of claim 1, wherein the balloon is unexpanded, at least a portion of the balloon distal cone portion is stored in the first recessed portion, and at least a portion of the balloon proximal cone portion is stored in the second recessed portion.

7. The catheter of claim 1, wherein said central shaft portion of the catheter tip further comprises a hub portion oriented beneath the balloon main body portion, the hub portion having a larger cross-sectional area than the central shaft portion.

8. The catheter of claim 7, wherein said catheter tip comprises a molded catheter tip and said hub portion is formed integrally with the catheter tip.

9. The catheter of claim 8, further comprising at least one marker.

10. The catheter of claim 9, wherein said radiopaque marker is insert molded.

11. The catheter of claim 9, wherein an outer surface of said radiopaque marker is flush with an outer surface of said catheter tip.

12. The catheter of claim 1, further comprising a stiffener.

13. The catheter of claim 12, wherein the stiffener is a spring.

14. The catheter of claim 1, wherein said catheter tip further comprises a marker region entrained with a radiopaque material.

15. The catheter of claim 1, wherein said catheter tip further comprises a first region and a second region, said first region having greater flexibility than said second region.

16. A catheter comprising:

a catheter shaft having a proximal end and a distal end;

an inflation balloon having a proximal waist portion, a proximal cone portion, a distal cone portion and a distal waist portion; and

a catheter tip having a proximal end, a distal end, a main shaft portion and a distal shaft portion, the catheter tip comprising a recessed portion, a cross-sectional area of the recessed portion being less than a cross-sectional area of the catheter tip at a location proximal to the recessed portion and at a location distal to the recessed portion, the recessed portion oriented beneath the balloon distal cone portion, in an unexpanded state at least a portion of the balloon being secured in the recessed portion; said catheter tip comprising a first region and a second region, said first region having greater flexibility than said second region; said catheter tip proximal end being coupled to said catheter shaft distal end, said balloon distal waist portion being attached to said catheter tip distal shaft portion; said catheter tip main shaft portion being substantially coextensive with said balloon;

wherein said second region comprises entrained stiffening fibers selected from a group consisting of polypropylene fibers and polyolefin fibers.

17. The catheter of claim 1, further comprising:

an outer catheter shaft;

wherein said balloon proximal waist portion is coupled to said outer catheter shaft.

18. The catheter of claim 1, wherein said catheter tip is coupled to said catheter shaft by heat bonding.

19. The catheter of claim 1, wherein said catheter tip is coupled to said catheter shaft by radio-frequency welding.

20. The catheter of claim 1, wherein said catheter tip is coupled to said catheter shaft with an adhesive.

21. The catheter of claim 1, wherein the catheter is a stent delivery catheter.

22. The catheter of claim 21, further comprising a stent mounted about the balloon.

23. The catheter of claim 22, wherein the stent is an inflation expandable stent.

24. The catheter of claim 22, wherein the stent is a self-expanding stent.

25. The catheter of claim 1, wherein at least a portion of the central shaft portion has a plurality of sides.

26. The catheter of claim 25, wherein the central shaft portion is triangular.

58. The catheter of claim 16, said catheter tip comprising a second recessed portion, a cross-sectional area of the second recessed portion being less than a cross-sectional area of the catheter tip at a location proximal to the second recessed portion and at a location distal to the second recessed portion;

wherein the balloon is unexpanded, at least a portion of the balloon distal cone portion is stored in said recessed portion, and at least a portion of the balloon proximal cone portion is stored in said second recessed portion.

59. The catheter of claim 15, wherein said second region comprises entrained stiffening fibers selected from a group consisting of carbon fibers, polypropylene fibers and polyolefin fibers.

60. The catheter of claim 1, wherein the balloon main body portion is cylindrical.

(ix) Evidence Appendix

None

(x) Related Proceedings Appendix

None